

## REMARKS

Applicants would like to thank the Examiner for the interview conducted today, October 28<sup>th</sup>, 2003, with Applicants' representatives, Laurie A. Axford (in person) and Nikolaos C. George (by telephone). During the interview, the following issues were discussed:

- 1) Support in the specification for the following limitation to claims 49, 55, 61 and 65: "wherein said SNPs are found in a general human population with about 25% or less frequency."
- 2) The Brennan reference, U.S. Patent No. 5,474,796 ("Brennan"), in connection with claim 49.
- 3) The language of claim 100, and the introduction of a limitation excluding hybridization to a wild-type nucleic acid.
- 4) Reintroduction of the cancelled array claims.

Claims 49-111 were pending and under consideration. Claims 112-122 were withdrawn from consideration. This Amendment is filed in response to the previous telephonic interviews and the recent in-person interview with Examiner Goldberg. With this Amendment, Claims 50-52, 56-58, 69-99, 101, 108-109, 113 and 120-122 have been cancelled. At the suggestion of Examiner Goldberg, claims 112 and 114 to 119 have been reintroduced. Claims 49, 53-55, 59-61, 65, 100, 102-107, 110-112 and 114 to 119 have been amended. New claim 123 is presented for the first time herein. Accordingly, after entry of the instant amendment, Claims 49, 53-55, 59-68, 100, 102-107, 110 to 112, 114 to 119 and 123 will be pending and under consideration.

### **I. AMENDMENT TO THE CLAIMS**

Claims 49, 55, 61, 65, 100, 102, 110 to 112, and 114 to 119 have been amended to recite, *inter alia*, that the polymorphism is a single nucleotide polymorphism or SNP. Support for the amendment can be found in the specification, for example, at Table 1.

Claims 49, 55, 61 and 65 have been amended to recite, *inter alia*, SNPs of SEQ ID NO:1 wherein said SNPs are found in a population with about 25% or less frequency. Support for this amendment can be found, for example, in the specification at page 12, lines 21 to 33. As described, the polymorphisms that occur in the general population about 25% or less of the time are preferred targets. Support for the amendment can also be found in the

specification in Table 2, wherein Table 2 is described as providing the frequency of the alleles at the polymorphic sites, with the preferred polymorphic sites that are specifically recited in the claims corresponding to the ones exhibiting 25% or less frequency in the general population.

Claims 49, 55, 61 and 65 have been amended to clarify any alleged uncertainty in the terms "at least about" as suggested by the Examiner. Support for the amendment can be found in the specification, for example, at page 13, line 22 to page 14, line 7. In addition, Claim 100 has been amended as suggested by the Examiner to delete the intended use language. Also, the recitation of "SEQ ID NO" has been amended to consistently omit the use of periods and the word "Claim" has been consistently capitalized.

Claim 100 was also amended at the suggestion of the Examiner to recite, *inter alia*, kits comprising an oligonucleotide comprising a sequence that hybridizes under stringent hybridization conditions to a SNP in a target nucleic acid at a SNP. Support for the amendment can be found in the specification, for example, at page 11, lines 6 to 22 and page 6, lines 11 to 26.

Amendments to reintroduced claims 112 and 114 to 119 were made to bring them into conformance with the amendments to the other claims as discussed above.

New Claim 123 is supported in the specification, for example, on page 6, lines 11 to 26; on page 13, lines 7 to 13; and page 14, lines 32 to 34. This claim is directed towards probes that are "specific" for the SNP, i.e. they hybridize to the SNP, but not to the wild-type sequence.

Applicants submit that the amendments are fully supported by the specification and the Claims as originally filed. Applicants respectfully request entry thereof.

## **II. The Brenner Patent**

During the interview today, the Applicants' representatives and the Examiner discussed the Brenner patent with respect to claim 49 and the inclusion of 8-mers. It is the Examiner's position that the Brenner patent anticipates all 10-mers and smaller oligonucleotide fragments. Applicants respectfully request reconsideration of this position.

Anticipation is established under 35 U.S.C. §102(b) when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. *Glaverbel Société Anonyme v. Northlake Mktg & Supply*, 45 F.3d 1550, 1554, 33 U.S.P.Q.2d 1496, 1498 (Fed. Cir. 1995). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates." *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999) (citation omitted). The fact that those of ordinary skill were unaware of inherent characteristics of the prior art is immaterial. *Id.*, 190 F.3d at 1347-8, 51 U.S.P.Q.2d at 1946-7 (citing *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985)); *Mehl/Biophile Intern. Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1305 (Fed. Cir. 1999).

The Brenner patent discloses a method for constructing an array representing every possible 10-mer (col. 9, lines 53 to 56.) Brenner does not disclose, either literally or inherently, each and every 10-mer in the array. A disclosure of a method to make something does not by itself disclose the product made. It cannot be disputed that Brenner does not adequately disclose every 10-mer, because Brenner does not put forward a utility or written description or enabling disclosure for all 10-mers. Thus, Brenner cannot anticipate the selected oligonucleotides that Applicants seek to patent. Even if Brenner were held to disclose the genus of all 10-mers, Applicants' invention is a selection invention directed towards only 13 specific SNPs in a single sequence (or its complement).

### **CONCLUSION**

Applicants thank the Examiner for her helpful comments and suggestions both telephonically and in person, and submit that the Claims in the case after entry of the amendments presented herein satisfy all the criteria for patentability and are in condition for allowance. An early indication of the same is therefore kindly solicited.

Applicants believe no fee is due with this Amendment. However, pursuant to 37 C.F.R. §1.136 (a)(3), the Commissioner is authorized to charge all required fees, fees under 37 C.F.R. §1.17 and all required extension of time fees, or credit any overpayment, to Pennie & Edmonds LLP, U.S. Deposit Account No. 16-1150 (Order No. 8907-057-999).

Respectfully submitted,

*Sam A. Cox, Reg # 35053*

Date: Oct 28, 2003

*for*

39,201

Nikolaos C. George

(Reg. No.)

**PENNIE & EDMONDS LLP**

1155 Avenue of the Americas

New York, New York 10036-2711

(212) 790-9090